



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: quinine sulfate

Brand Name: Qualaquin

Medication Class: antimalarial

FDA Approved Uses: treatment of uncomplicated *Plasmodium falciparum* malaria.

Available Dosage Forms: 324mg capsules

Usual Dose: 648mg (two capsules) every 8 hours for 7 days

Duration of Therapy: 7 days

Approximate cost (based on AWP 2007): \$183.75 for 7 day therapy

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Must have an infectious disease consult
- Must be clinically diagnosed with uncomplicated *Plasmodium falciparum* malaria and being used for treatment only
- Must be 16 years of age or older

Cautions:

- Use should be avoided in patients with known QT prolongation, elderly, and in patients with clinical conditions known to prolong QT interval (such as uncorrected hypokalemia, bradycardia, and certain cardiac conditions)
- Not recommended for use with other drugs known to cause QT prolongation (e.g. quinidine, procainamide, disopyramide, amiodarone, sotalol, dofetilide)
- Not recommended for use with drugs that are CYP3A4 substrates known to cause QT prolongation (e.g., astemizole, cisapride, pimozide, halofantrine, quinidine)
- Not recommended for use with antimalarial drugs mefloquine or halofantrine
- Use of macrolide antibiotics, rifampin, antacids, and neuromuscular blocking drugs should be avoided
- Serious hypersensitivity reactions have been reported. Qualaquin should be discontinued in case of any signs or symptoms of hypersensitivity.
- Should be used with caution in patients with atrial fibrillation or atrial flutter
- Patients, especially pregnant women, may experience hypoglycemia.

Monitoring:

- Monitor patients on digoxin, warfarin, drugs that are CYP2D6 substrates (e.g., desipramine, flecainide, dextromethorphan, metoprolol, paroxetine), anticonvulsants, cimetidine, ketoconazole, tetracycline, urinary alkalizers (acetazolamide, sodium bicarbonate), theophylline or aminophylline.



Contraindications:

- prolonged QT interval
- glucose-6-phosphate dehydrogenase (G-6-PD) deficiency
- myasthenia gravis
- hypersensitivity to quinine, mefloquine, quinidine
- optic neuritis

Not Approved if:

- Patient has severe or complicated *P. falciparum* malaria
- Being used for the prevention of malaria
- Being used for the treatment or prevention of nocturnal leg cramps*
- Patient does not meet the above criteria
- Patient has any contraindication to the use of quinine sulfate

Special Considerations:

- *Use of Quaaliquin for nocturnal leg cramps: Quaaliquin may cause unpredictable serious and life-threatening hypersensitivity reactions, QT prolongation, serious cardiac arrhythmias, and other serious adverse events requiring medical intervention and hospitalization. The risk associated with the use of quinine sulfate in the absence of evidence of its effectiveness for the treatment or prevention of nocturnal leg cramps, outweighs any potential benefit in treating and/or preventing the benign, self-limiting condition.
- Dose reduction not warranted in patients with mild to moderate hepatic impairment, but should be monitored
- The effects of severe hepatic impairment are not known
- For severe chronic renal failure, a modified dose should be used: one loading dose of 648mg followed 12 hours later by maintenance doses of 324mg every 12 hours
- The effects of mild and moderate renal impairment are not known

P&T Approval: _____ Date: _____